IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA

UNITED STATES OF AMERICA *ex rel.* Darryl Landis, M.D. Plaintiff, v. GENOVA DIAGNOSTICS, INC., GNVA HOLDINGS, INC., GNVA EQUITY HOLDCO., INC., LEVINE LEICHTMAN CAPITAL PARTNERS V, L.P., LAUREN LEICHTMAN, AARON PERLMUTTER, CHRIS SMITH, and JOHN DOES 1-10 Defendants.	Hand-Delivered 1:17-cv-341-MR-DLH **COMPLAINT** **(Jury Trial Demanded)** **DO NOT PLACE IN PRESS BOX** **DO NOT ENTER IN PACER**

FILED IN CAMERA AND UNDER SEAL
Pursuant to 31 U.S.C. § 3730(b)(2) & N.C. Gen. Stat. § 1-608(b)(2)

Qui Tam Relator Dr. Darryl Landis ("**Relator**" or "**Dr. Landis**") brings this action on his own behalf and on behalf of the United States of America to recover civil damages for violations of the Federal False Claims Act.

I. THE PARTIES

1. Plaintiff Darryl Landis, M.D., is a North Carolina resident.

2. Defendant Genova Diagnostics, Inc. ("**Genova**") is a Delaware corporation having its principal place of business at 63 Zillicoa Street Asheville, NC 28801-1038.

3. GNVA Holdings, Inc. ("**GNVA**") is a Delaware corporation which, upon information and belief, has a principal place of business in Asheville, North Carolina.

4. GNVA Equity Holdco., Inc. ("**GNVA Equity Holdco.**") is a Delaware corporation which, upon information and belief, has a principal place of business in Asheville, North Carolina.

5. Upon information and belief, Defendant Levine Leichtman Capital Partners V, L.P. ("**LLCP**"), is a Delaware limited partnership with its principal place of business at 335 North Maple Drive, Suite 130, Beverly Hills, California 90210.

6. Defendant Chris Smith ("**Smith**") is President and Chief Executive Officer of Genova and a member of the Board of Directors of GNVA Holdings, Inc., and Genova Diagnostics, Inc. Upon information and belief, Mr. Smith is a resident of North Carolina.

7. Defendant Lauren Leichtman ("**Leichtman**") is a member of the Board of Directors of GNVA Holdings, Inc., and Genova Diagnostics, Inc. Upon information and belief, Ms. Leichtman is a resident of California.

8. Defendant Aaron Perlmutter ("**Perlmutter**") is a member of the Board of Directors of GNVA Holdings, Inc., and Genova Diagnostics, Inc. Upon information and belief, Mr. Perlmutter is a resident of California.

9. Upon information and belief, Defendants Leichtman and Perlmutter are partners in or employees of LLCP. Defendants Leichtman and Perlmutter are collectively referred to as the "LLCP Directors."

10. John Does 1-10 are unidentified officers and directors of GNVA Holdings, GNVA Equity Holdco., LLCP, or Genova Diagnostics and unidentified partners in or employees of those entities who had knowledge of, the fraudulent conduct detailed herein.

II. JURISDICTION AND VENUE

11. This action arises under the FCA, as amended, 31 U.S.C. § 3729, *et seq.*, and under the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605, *et seq.* The Court has

jurisdiction over this action under 31 U.S.C. § 3730(b) and § 3732(b) and 28 U.S.C. § 1331 and § 1367(a).

12. Venue is proper in the Western District of North Carolina pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a).

13. This Court may exercise personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a).

III. LEGAL FRAMEWORK

A. The Federal False Claims Act

14. The Federal False Claims Act provides, in relevant part, that any person who:

> (A) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (B) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . .
>
> Is liable to the Unites States Government for a civil penalty of not less than [$10,957] and not more than [$21,916] . . . plus 3 times the amount damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1). For purposes of the FCA,

> (1) The terms "knowing" and "knowingly"—
>
> (A) mean that a person, with respect to information—
>
> (i) has actual knowledge of the information;
>
> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
>
> (iii) acts in reckless disregard of the truth or falsity of the information; and
>
> (B) require no proof of specific intent to defraud[.]

31 U.S.C. § 3729(b)(1).

B. The North Carolina False Claims Act

15. Like the Federal False Claims Act, the North Carolina False Claims Act, N.C. Gen. Stat. § 1-607 also provides that any person who

> (1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval [or]
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim

shall be liable for treble damages and pay a civil money penalty for each violation. The definition of "knowing" and "knowingly" is also substantially similar to the Federal False Claims Act. See N.C. Gen. Stat. § 1-606(4).

C. The Medicare Program

16. Congress enacted the Medicare program, codified at Title VII of the Social Security Act, 42 U.S.C. § 1395, et seq., in 1965. The Center for Medicare & Medicaid Services ("CMS") administers the Medicare program.

17. CMS contracts with private contractors, variously referred to as "fiscal intermediaries," "carriers," or Medicare Administrative Contractors ("MACs"), to act as agents in reviewing and paying claims submitted by health care providers. Medicare consists of four parts: A, B, C, and D. Genova billed Medicare under Part B, which covers medical services such as clinical laboratory tests. 42 U.S.C. § 1395k(a)(2)(B).

18. To participate in the Medicare program, independent clinical laboratories such as Genova must submit a Medicare Enrollment Application, CMS Form-855B. Laboratories must also complete Form CMS-855B to change information or to reactive, revalidate and/or terminate Medicare enrollment.

19. The regulations governing Medicare require providers and suppliers to certify that they meet, and will continue to meet, the requirements of Medicare statute and regulations. See 42 C.F.R. § 424.516(a)(1).

20. An authorized official must sign the "Certification Section" in Section 15 of Form CMS-855B.

21. Authorized officials for Genova signed the certification statement in Section 15 of Form CMS-855B. In doing so, they indicated that they understood that Genova was required to comply with applicable Medicare laws, regulations and program instructions. The authorized officials further certified that they would not "knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare" or "submit claims with deliberate ignorance or reckless disregard of their truth or falsity."

22. To obtain Medicare and Medicaid reimbursement, providers and suppliers submit a claim form known as the CMS 1500 form, or its electronic equivalent known as the 837P form.

23. The CMS 1500 or 837P requires that the provider or supplier identify each service or item provided using a five-digit code. Current Procedural Terminology codes ("CPT codes") are typically used to report services provided to patients, while Healthcare Common Procedure Coding System codes ("HCPCS codes") are typically used to report devices, equipment or supplies provided to patients.

24. In addition, the Form 1500 or 837P requires a healthcare professional to report diagnoses that provide a basis for the selected code using International Classification of Diseases, 10th revision, Clinical Modification (ICD-10-CM) codes.[1]

[1] Prior to October 1, 2015, healthcare providers used ICD-9 codes for diagnoses.

D. Regulations Regarding Coverage for Laboratory Tests

25. Medicare only covers services that are medically necessary. Medicare.gov defines "medically necessary" as "health care services or supplies needed to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine."

26. Medicare will only reimburse claims for diagnostic laboratory services that are reasonable and necessary for the diagnosis or treatment of an illness. *See* 42 U.S.C. § 1395y(a)(1)(A).

27. To be eligible for coverage, diagnostic laboratory tests "must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." 42 C.F.R. § 410.32(a).

28. The Medicare Benefit Policy Manual ("MBPM") details CMS's policies for payment of Medicare benefits. MBPM's "Requirements for Ordering and Following Orders for Diagnostic Tests" define an "order" as "a communication from the treating physician/practitioner requesting that diagnostic test be performed for a beneficiary . . . [T]he physician must clearly document, in the medical record his or her intent that the test be performed." MBPM, Ch. 15, § 80.6.1.

29. North Carolina's Medicaid program also requires that testing be individualized to the medical needs of patients. As stated in § 3.1 of the NC Division of Medical Assistance Laboratory Services Clinical Coverage Policy No: 1S-3:

> Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:

a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs . . . .

(available at https://files.nc.gov/ncdma/documents/files/1S-3_0.pdf)

30. In addition, 10A N.C.A.C. § 25A.0201 provides that "[a]ll medical services performed must be medically necessary and may not be experimental in nature. Medical necessity is determined by generally accepted North Carolina community practice standards as verified by independent Medicaid consultants."

31. Laboratories, like Genova, have a legal duty to ensure that they do not submit claims to Medicare or Medicaid for medically unnecessary tests.

32. In regard to that duty, the Office of the Inspector General for the Department of Health and Human Services ("the OIG") recommends that labs have requisition forms that "promote the conscious ordering of tests by physicians" and "ensure that the physician . . . has made an independent medical necessity decision with regard to each test the laboratory will bill." OIG Guidance, 63 Fed. Reg. 45,075, at 45,079.

IV. FACTUAL ALLEGATIONS

I. Overview of Genova Diagnostics and Its Clinical Laboratory Products.

A. Genova Diagnostics

33. Genova Diagnostics is a specialty clinical laboratory focused on the "functional" medicine market.

34. Functional medicine is a form of alternative medicine that focuses on potential interactions between the environment and the gastrointestinal, endocrine, and immune systems.

35. Founded in 1986, Genova's niche in the functional medicine market is to provide clinical laboratory tests to functional medicine practitioners that such practitioners believe will assist in developing treatment plans for their patients.

36. In 2013, Genova became a wholly-owned subsidiary of Defendant GNVA Holdings, Inc. ("GNVA"). Upon information and belief, GNVA Equity Holdco. and LLCP are the controlling shareholders of GNVA. The LLCP Directors constitute a majority of the Board of Directors of both GNVA and Genova.

B. Genova's GI Effects Panel

37. Genova offers a panel of fecal stool tests, the GI Effects 2200 ("**GI Effects Panel**"),[2] that encompasses tests for and assesses 46 different biomarkers of gastrointestinal function, including 24 commensal bacterial targets found in the gastrointestinal system.

38. Commensal bacteria are non-infectious bacteria present at some level in many healthy individuals and have not been shown to cause disease, do not indicate any specific treatments, and are not part of any generally accepted standard of care.

39. Genova markets the GI Effects Panel as "an advanced stool test that provides immediate, actionable clinical information for the management of gut health." More specifically, Genova claims that the GI Effects Panel, among other things, "assesses 24 commensal bacteria associated in the scientific literature with health and disease, and provides valuable insight into the human microbiome."

40. Genova recommends the GI Effects Panel for use in diagnosing and/or formulating treatment plans for a wide range of clinical conditions, including irritable bowel syndrome (IBS), inflammatory bowel disease (IBD), diabetes, obesity, cardiovascular disease, celiac and other malabsorption disorders, mood disorders, autism, and autoimmune disorders.

[2] In addition to the GI Effects 2200 panel, Genova offers a variety of gastrointestinal tests that use the same methodologies and test for many of the same biomarkers as the GI Effects 2200 panel. Thus, the allegations in the Complaint as to GI Effects 2200 panel are illustrative and representative of problems endemic to all of Genova's gastrointestinal tests.

41. Contrary to Genova's marketing claims, the GI Effects Panel is not reasonable or medically necessary for the diagnosis or treatment of any illness.

42. There are no published, peer-reviewed studies or papers that assess the clinical validity and utility of the GI Effects Panel for any of the conditions identified above in paragraph 40.

43. The GI Effects Panel utilizes proprietary testing platforms and algorithms that are unpublished and not adequately validated.

44. There are no high-quality clinical studies demonstrating the validity, utility, and cost-effectiveness of the GI Effects Panel in clinical practice.

45. The GI Effects Panel does not meet accepted standards of medical practice.

46. In fact, numerous private payers (e.g., insurance companies) have published numerous adverse medical policies specifically identifying the tests on the GI Effects Panel as not medically necessary.

47. When billing Medicare, NC Medicaid, and other government payers for the GI Effects Panel's tests, Genova also uses incorrect CPT codes.

48. For example, Genova uses CPT code 87798 for each of the 24 commensal bacteria targets tested in the GI Effects Panel.

49. CPT code 87798 applies to "infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism."

50. In other words CPT code 87798 applies to tests to detect "infectious agent[s]" that are not otherwise covered by a CPT code.

51. CPT code 87798 is not appropriate for the 24 commensal bacterial targets assessed by GI Effects panel because those bacteria are not infectious agents.

52. In submitting claims for Medicare and NC Medicaid payment of the GI Effects Panel's tests that analyze non-infectious gut bacteria, Genova falsely represents that the 24 commensal bacteria test panels are "infectious agent" tests.

53. The 24 bacterial targets tested by the GI Effects Panel are in fact commensal organisms that have not been definitively demonstrated in the any published literature to cause disease or infections.

54. None of the 24 commensal bacterial targets in the GI Effects Panel have been shown in published literature to cause any of the associated ICD 10 conditions.

55. Another seven CPT codes associated with the GI Effect Panel (82542; 82784; 82725; 82715; 83520; 84311; 87102) also lack sufficient clinical validity and/or utility for routine use with any of the ICD 10 conditions.

56. The tests billed with these seven codes are not generally accepted standard of care for any ICD 10 conditions.

57. The remaining 11 CPT codes may have appropriate and medically necessary indications for patients with one or more of the listed ICD 10 conditions on an individual case basis. However, it is not a generally accepted standard of care to routinely order all of those tests simultaneously and without regard to the relevancy of each test's utility for the diagnosis or treatment of any particular individual.

58. Genova nonetheless offers a "check the box" requisition form for the GI Effects Panel whereby a single check mark by the provider orders the entire panel of 46 tests for billing purposes. See **Exhibit 1**.

59. Genova's "check the box" form interferes with providers' medical judgment by preventing them from ordering only the specific tests that the provider has deemed medically

necessary for the particular patient. In other words, Genova's requisition form does not ensure that the physician is making an independent medical necessity decision with regard to each of the GI Effects Panel's tests.

60. The requisition form therefore results in physicians' ordering of and Genova's knowing submission of Medicare and Medicaid claims for payment of medically excessive and unnecessary tests.

61. Upon information and belief, Genova has submitted to Medicare claims for payment and received from Medicare substantial sums for medically unnecessary GI Effects Panel tests. For the July 1, 2015-June 30, 2017, time period, Genova received at least $8,916,899 from Medicare for GI Effects Panels.

62. Upon information and belief, Genova has submitted to North Carolina Medicaid claims for payment and received from North Carolina Medicaid funds for medically unnecessary GI Effects Panels.

C. Genova's NutrEval Panels

63. Genova has two NutrEval Panels: the NutrEval FMV Test, and the NutrEval Plasma Test (together, the "**NutrEval Panels**").

64. Genova promotes the NutrEval Test FMV (First Morning Void) test as "an advanced diagnostic tool to guide nutritional therapies, often augmenting and speeding recovery of complex chronic conditions." https://www.gdx.net/product/nutreval-fmv-nutritional-test-blood-urine (as of December 7, 2017).

65. Per Genova, the NutrEval FMV Test "identifies nutritional deficiencies that may be a *causative* factor in complex chronic conditions." *Id.* (emphasis added).

66. Genova markets the second NutrEval Panel, the NutrEval Plasma test, as "reveal[ing] nutritional imbalances or inadequacies." https://www.gdx.net/product/nutreval-

nutritional-test-plasma (as of December 7, 2017). Genova advertises the Plasma test as "a nutritional analysis that allows assessment of nutritional inadequacies or imbalances that may be playing a causative role in complex chronic conditions."

67. Genova recommends both NutrEval Panels for individuals who suffer from mood disorders, fatigue, digestive complaints, chronic pain, inflammatory conditions, cardiovascular risk, and weight issues. *Id.*

68. The NutrEval Panels evaluate and test over 100 organic acids, amino acids, fatty acids, micronutrients, and other elements in an individual's blood and urine.

69. Contrary to Genova's marketing claims, the NutrEval Panels are not reasonable or necessary for the diagnosis or treatment of any illness.

70. There are no published, peer-reviewed studies or papers that assess the clinical validity and utility of the NutrEval Panels for any of the identified conditions.

71. The NutrEval Panels utilize proprietary testing platforms and algorithms that are unpublished and not adequately validated.

72. There are no clinical studies establishing the validity, utility, and cost-effectiveness of the NutrEval Panels in clinical practice.

73. The NutrEval Panels do not meet accepted standards of medical practice.

74. Like the GI Effects Panel, Genova's requisition form for the NutrEval Panels has a single check box that does not differentiate between the 100 plus test targets or allow physicians to deselect tests that are irrelevant to and medically unnecessary for their patients. The ordering form therefore does not ensure that the physician has made an independent medical necessity decision with regard to each of the NutrEval Panel's tests.

75. As a result, by checking the box for the NutraEval Panels, a physician orders the entire panel of tests, regardless of whether the majority of the 100 plus test targets are medically unnecessary to prevent, diagnose, or treat a patient's illness, injury, condition, disease, or symptoms. As a further consequence, Genova then knowingly submits claims for Medicare and Medicaid payment for medically excessive and unnecessary tests in the NutrEval Panels.

76. Genova has submitted to Medicare claims for payment for and Medicare has reimbursed Genova substantial sums for medically unnecessary NutrEval Panels. Upon information and belief, for the July 1, 2015, through June 30, 2017 time period, Medicare paid Genova $6,275,460 for NutrEval Panels.

77. Genova also has submitted to North Carolina Medicaid claims for payment and received from North Carolina Medicaid funds for medically unnecessary NutrEval Panels.

D. Hormone Panels:

78. Genova's Hormone Panel tests include: (1) the Menopause Plus and Menopause Check Plus salivary hormone panel tests that evaluate sex hormones in men and women; (2) the Rhythm salivary hormone panel test, which assesses estradiol, progesterone, and testosterone over a 28 day period; and (3) the Complete Hormones urinary panel test, which "assesses parent hormones, their metabolites, and key metabolic pathways," *See, e.g.*, https://www.gdx.net/product/complete-hormones-test-urine (as of December 8, 2017).

79. Genova markets the Hormone Panel tests as assisting "in the clinical management of hormone-related conditions," and recommends the Panels to help guide hormone replacement therapy and for men and women suffering from "weight gain, anxiety, fatigue, low sex drive and performance issues, sleep disturbances, mood instability, brain fog, and hot flashes." *Id.*

80. Although Genova bills Medicare and Medicaid for the Hormone Panels, there is no clinical evidence that the Panels are medically necessary.

81. Specifically, several of the Hormone Panels involve urine specimens, which are not standardly used in the medical community to analyze sex hormones as there is no medical literature or clinical evidence that such specimens have any utility to the diagnosis or treatment of hormonal (or any) diseases or illnesses.

82. The Hormone Panels' salivary tests also are not clinically proven to be medically necessary to the patient population in general and have been determined by be unreliable by major national professional organizations, including, but not limited to, the American Association of Clinical Endocrinologists and the American College of Obstetricians and Gynecologists.

83. Although select salivary tests, such as ones for cortisol levels, may be relevant and medically necessary to a very select patient population, Genova's Hormone Panels are not limited to those salivary tests, but instead include a bundle of other medically unnecessary tests.

84. There are no peer-reviewed clinical studies that support the medical necessity of the Hormone Panels' array of tests.

85. As with Genova's other tests, many private insurance companies deny coverage for the Hormone Panels.

86. Despite actual knowledge that there is insufficient evidence to support the medical necessity and validity of the Hormone Panels, Genova, at the direction of the other Genova Defendants, systematically submits claims for payment for the Hormone Panels to Medicare and Medicaid, and, in doing so, fraudulently certifies to Medicare and other government payers, including North Carolina Medicaid, that the Hormone Panels are in fact medically necessary.

87. Upon information and belief, for the July 1, 2015, through June 30, 2017, time period, Genova has submitted to Medicare claims for payment and Medicare has reimbursed $1,584,351 for medically unnecessary Hormone Panels.

88. Genova also has submitted to North Carolina Medicaid claims for payment and received from North Carolina Medicaid funds for medically unnecessary Hormone Panels.

E. The IgG Food Antibody Panel:

89. Genova's website promotes the IgG Food Antibody Panel as "a food sensitivity test which helps identify those with true IgE-mediated allergies as well as IgG-mediated food intolerances." https://www.gdx.net/product/igg-food-antibodies-food-sensitivity-test-blood (Last Checked December 13, 2017).

90. Genova claims that this Panel "is ideal for patients who may suffer from delayed reactions/sensitivities to specific foods. It may also provide insight on intolerances, or non-immune responses, to certain foods." Id.

91. The IgG Food Antibody Panel measures and tests 80 plus food antibody targets. Genova's Requisition Form for this Test has a single check box that does not differentiate between the 80 targets or allow physicians to deselect targets that are irrelevant to their patients. The form therefore does not ensure that the physician has made an independent medical necessity decision with regard to each test for which Genova will bill Medicare/Medicaid.

92. As a result, by checking the box for the IgG Food Antibody Panel, a physician automatically orders the entire panel of tests, regardless of whether the majority of the 80 test targets are medically unnecessary to prevent, diagnose, or treat his/her patient's illness, injury, condition, disease, or symptoms.

93. Genova then bills Medicare/Medicaid for all 80 of the Panel's food antibody targets, fraudulently certifying that the Panel (and all of its tests) was medically necessary.

94. There is no clinical evidence that the IgG Food Antibody Panel is medically necessary.

95. Because the IgG Food Antibody Panel simultaneously measures 80 plus food antibody targets, the Panel typically demonstrates some results outside of the reference range even in *healthy* individuals.

96. There are no published or internal Genova studies that evidence that the patterns of Genova's IgG food antibody levels actually differ between healthy and unhealthy individuals.

97. Consequently, abnormal results for the IgG Food Antibody Panel do not indicate any specific diagnosis or recommended treatment for an individual, and the Panel is not part of the generally accepted standard of care.

98. There are no peer reviewed papers assessing the clinical validity or utility of the IgG Food Antibody Panel.

99. A number of clinical care guidelines refer conclude that: "food-specific IgG4 does not indicate (imminent) food allergy or intolerance, but rather a physiological response of the immune system after exposition to food components. Therefore, testing of IgG4 to foods is considered as irrelevant for the laboratory work-up of food allergy or intolerance and should not be performed in case of food-related complaints."

100. Medicare and Medicaid will not provide coverage for investigational services, like this Panel, that have not yet been established as medically necessary and an accepted standard of medicine.

101. Despite the lack of evidence that the IgG Food Antibody Panel meets Medicare's requirement of medical necessity, Genova systematically bills Medicare and Medicaid for the IgG Food Antibody Panel (and its entire panel of 80 food antibody test targets).

102. Upon information and belief, for the July 1, 2015, through June 30, 2017 time period, Genova has submitted to Medicare claims for payment and Medicare has reimbursed $4,853,798 for medically unnecessary IgG Food Antibody Panel.

103. Genova also has submitted to North Carolina Medicaid claims for payment and received from North Carolina Medicaid funds for medically unnecessary IgG Food Antibody Panels.

F. In Summary:

104. For at least the July 1, 2015, through June 30, 2017, time period (and, in some cases, as early as 2010), Defendants systematically and fraudulently submitted or caused to be submitted claims for Medicare/Medicaid payment for the GI Effects Panel, NutraEval Panel, Hormone Panels, and IgG Food Antibody Panel, and they did so with actual knowledge that none of the Panels are medically necessary, meet accepted standards of medicine, or are eligible for Medicare or Medicaid payment.

105. Additionally, with regard to the GI Effects Panel, Defendants fraudulently and knowingly billed (or caused to be billed) Medicare and Medicaid with an incorrect and misleading CPT code.

106. During that time period, Defendants also wrongly utilized requisition forms with a single box order format that required physicians to automatically order a large number of tests without an individualized assessment of which of the many tests may be reasonable and (allegedly) medically necessary for the treatment and diagnosis of his/her individual patient's illness. As a result, the requisition form resulted in the ordering of and Genova's performing of excessive and medically unnecessary tests.

107. In turn, Defendants then knowingly and fraudulently submitted or caused to be submitted to Medicare and Medicaid claims for payment for those medically excessive and unnecessary Panels.

II. Defendants' Knowledge of Genova's Compliance Issues and Fraudulent Billing Practices.

A. Dr. Landis's Role at and Investment in Genova

108. Genova has known since at least 2010 that its nonconventional tests lack requisite medical necessity evidence to be eligible for Medicare and Medicaid payment.

109. During the 2010-2012 time period, Genova's then CMO, Patrick Hanaway, initiated clinical development efforts in an attempt to develop such evidence.

110. In July of 2012, Genova hired Dr. Landis to be its new CMO and tasked him with developing medical necessity evidence for its tests.

111. Dr. Landis is a board-certified physician, family medicine practitioner, physician executive, and adjunct professor at a leading academic medical center.

112. Ted Hull, the former CEO of Genova, hired Dr. Landis in July 2012 because Dr. Landis was a conventionally-trained physician with deep expertise in medical policy, clinical research, and evidence-based care.

113. After he joined Genova as the CMO, Dr. Landis helped form and execute a clinical evidence development strategy so that Genova could develop reliable scientific evidence to establish the medical necessity of its various tests.

114. Dr. Landis initially secured significant budget authority to pursue the clinical evidence development strategy. Mr. Hull, and the Company's Chief Marketing Officer, Chris Smith, expressed that they were firmly committed to a clinical evidence development strategy.

Indeed, the Company had budgeted $1 Million for a certain clinical evidence study to be conducted by the Company.

115. As detailed above, LLCP, as controlling shareholder of GNVA, acquired Genova in 2013. As one of the four Key Managers and CMO of Genova, Dr. Landis fully participated in and contributed to all aspects of the sales process, including all management presentations to LLCP.

116. In those meetings and in diligence, there was ample discussion of the clinical evidence strategy, and the imminent $1M clinical study, which had been approved and budgeted. In reliance on LLCP's stated commitment to that strategy, Dr. Landis made a significant financial investment in the Company, and was even induced to borrow money from the Company and GNVA to acquire additional equity in the Company. At present, Dr. Landis and a limited liability company in which he is a member own 7,691 common shares in the Company through the GNVA entities, and he has been granted over 35,000 stock options, the majority of which are fully vested.

117. In connection with LLCP's acquisition of Genova, Dr. Landis entered into an Employment Agreement with the Company dated September 29, 2013. On November 13, 2013, Dr. Landis executed and entered into the GNVA Holdings, Inc. Stockholders Agreement, the GNVA Holdings, Inc. 2013 Stock Option Plan, and the GNVA Holdings, Inc. Non-Qualified Stock Option Agreement, as well as signing promissory notes with the Company and GNVA to secure the money loaned to him to purchase equity in the Company and GNVA.

B. Dr. Landis Warnings to Defendants About Fraudulent Billing Practices

118. As outlined below, Dr. Landis has repeatedly raised concerns about and warned Defendants about the weak to non-existent clinical support for the medical necessity of Genova's

panel tests, including the GI Effects Panel, and the resulting propriety of Genova's Medicare and Medicaid billing of those tests.

119. Following LLCP's acquisition, Genova's then CEO, Ted Hull, left the Company. In his place, LLCP promoted Chris Smith to CEO.

120. Under Chris Smith's tenure, the marketing arm of Genova has wielded significant power at Genova to the detriment of the Company, generally, and to Dr. Landis' Medical Affairs Team and Genova's clinical evidence strategy in particular.

121. Dr. Landis attempted several other large-scale definitive clinical evidence development initiatives, which were never approved by Chris Smith or LLCP.

122. While it was becoming increasingly clear that LLCP and Chris Smith had no intention of executing on the clinical evidence strategy, private payers and Medicare began raising questions about the medical necessity justifying the use of billing codes used for certain of Genova's tests.

123. Specifically, on July16, 2015, Genova received a notification from Blue Cross Blue Shield – Federal Employee Processing regarding a negative medical policy determination related to Genova's stool testing.

124. Dr. Landis notified Genova's CEO, Mr. Smith, as well as Genova's CFO and Vice-President of Sales, regarding this negative policy determination.

125. On July 23, 2015, Dr. Landis voiced concern to Mr. Smith that almost none of Genova's tests met the medical necessity criteria necessary to bill Medicare, and reiterated that Genova needed to invest time and money in developing clinical evidence to support such medical necessity and Medicare eligibility.

126. Subsequently, Genova received a notice that CMS was placing Medically Unnecessary Edit ("MUE") on Genova's use of certain CPT codes.

127. As a result of the MUE, Dr. Landis recommended that Genova undertake a review of its coding and billing practices.

128. In connection with that effort, Dr. Landis became aware in February 2016 that Genova was billing for the GI Effects test using CPT code 87798.

129. Around that same time, Dr. Landis expressed concern to Genova's leadership team, including Smith, about the use of CPT code 87798 (a code for infectious agent detection) for the GI Effects Test, which analyzes non-infectious bacteria.

130. As a result of Dr. Landis's concerns, Genova asked Boston Healthcare Associates ("BHA") to review the propriety of using CPT 87798 for the GI Effects Test.

131. In August 2016, Dr. Landis asked about the results of the BHA analysis. In response, he received a copy of a June 10, 2016 report (the "BHA Report").

132. Problematically, the BHA report, which was only 1.5 pages long, did not address (i) the medical necessity of testing for commensal bacteria or (ii) the inconsistency between the code description of "infectious" compared with the "commensal" nature of the targeted bacteria. The report itself also noted that coding experts consulted by BHA "provided variable guidance on the most appropriate coding strategy."

133. Throughout the Fall of 2016, Dr. Landis continued to propose additional clinical evidence development initiatives for Genova's tests, none of which Genova (or its controlling entities) agreed to pursue.

134. On December 13, 2016, Dr. Landis prepared a detailed memo outlining his fraud concerns with respect to: (a) the use of CPT code 87798 for the GI Effects Panel, and (b)

whether there was clinical evidence to support the medical necessity of, and therefore and ability to bill Medicare for, the GI Effects Panel's tests. Dr. Landis submitted that memo to Genova's Compliance Hotline and to Genova's Board members, including Aaron Perlumutter, David Burcham, David Reed, and David Zewe.

135. Without a substantive response from Defendants about that memo's fraud concerns, Dr. Landis continued to warn that Genova's Medicare billing for the tests was not appropriate, and continued to express those good faith concerns multiple times throughout 2016 and 2017.

136. For example, in June of 2017, Dr. Landis emailed Smith and Genova's CFO, Vice President of Sales, Compliance Officer, and Lab Director to recommend that Genova stop billing Medicare for allergy testing as there was a lack of requisite clinical evidence to establish those tests' medical necessity. Defendants refused to heed that warning and continued to bill Medicare and Medicaid for those tests.

137. On August 3, 2017, Dr. Landis spoke with Perlmutter and Leichtman, two members of GNVA Holding's and Genova's Board of Directors, about his fraud concerns. During that conversation, Dr. Landis told Perlmutter and Leictman that, in his professional assessment as Genova's CMO, Genova's tests do not meet Medicare's requirements for medical necessity, and that Genova's continued billing of Medicare for those tests could have devastating financial and legal consequences.

138. The following month, on September 7, 2017, Genova and GNVA Holdings finally responded in writing to Dr. Landis' concerns about Genova's use of the CPT code 87798 for the GI Effects Panel.

139. According to Genova and GNVA holdings, Genova had engaged healthcare counsel and hired an expert, Joel Brill, M.D., to review the use of CPT code 87798.

140. According to Genova, Dr. Brill had produced a 12-page report dated February 13, 2017.

141. Upon information and belief, that report, which was based on a literature review limited to the issue of whether commensal bacteria can be infectious and pathologic, concluded that Genova's use of CPT code 87798 was appropriate.

142. Genova has refused to provide a copy of Dr. Brill's report to Dr. Landis's despite repeated requests.

143. Upon information and belief, Dr. Brill's report does not address the fundamental fraud concern raised by Dr. Landis; i.e., whether there is any clinical evidence to support the medical necessity of the GI Effects Panel.

144. On further information and belief, Genova deliberately limited the scope of Dr. Brill's assignment and provided him with limited information in order to secure a conclusion that supported Genova's continued use of CPT code 87798 for Medicare and Medicaid billing purposes.

145. Upon information and believe, Genova's activities with regard to the inadequate investigation of Dr. Landis's claims were conducted with the full knowledge and approval of Genova's Board of Directors, including the LLCP Directors.

146. Since being informed of Dr. Landis's repeated concerns regarding Genova's improper billing practices, Defendants have not taken any action to end Genova's fraudulent billing practices.

C. Defendants Retaliate Against Dr. Landis.

147. In the Spring of 2016, as Dr. Landis communicated with Mr. Smith regarding his good faith and legitimate concerns about the lack of clinical evidence to support Genova's products and billing, Mr. Smith chastised Dr. Landis both for expressing his opinions and creating a record of them.

148. Soon after, Mr. Smith met with direct reports of Dr. Landis without Dr. Landis' knowledge, and attacked and criticized Dr. Landis and his "overly conservative" point of view on the clinical evidence, and outlined his personal and professional disagreements with Dr. Landis.

149. Mr. Smith also sought to undermine Dr. Landis with Genova leadership and staff. Mr. Smith repeatedly initiated meetings with members of the team led by Dr. Landis, alone and without Dr. Landis' knowledge, for the purpose of fomenting discord and distrust, to fish for negative information about Dr. Landis, and to further isolate Dr. Landis.

150. Mr. Smith repeatedly attacked and criticized employees of the Company who shared Dr. Landis' views or whom Mr. Smith viewed as aligned with Dr. Landis, ultimately forcing them out of the Company.

151. On June 1, 2016, Mr. Smith directed that Dr. Landis was not to utilize Medical Affairs personnel for any tasks unless specifically authorized by Mr. Smith.

152. That directive marked a substantial limitation of Dr. Landis' authority and role as Chief Medical Officer of Genova and constituted a material change in Dr. Landis' job duties

153. That directive by Mr. Smith also significantly hampered Dr. Landis' ability to plan ahead for new product research and development.

154. On October 21, 2016, Mr. Smith prepared a negative annual performance appraisal for Dr. Landis, and questioned why Dr. Landis did not leave the Company. All of Dr.

Landis' prior performance appraisals had been positive. Dr. Landis objected to the negative appraisal and disputed the core negative criticisms of Mr. Smith.

155. On December 21, 2016, Dr. Landis complained to Ms. Earlene Clark, the Company's Compliance Officer, and sought her intercession to have Mr. Smith's ongoing and continuous actions in retaliation against him stop.

156. In their discussion, Dr. Landis told Ms. Clark that Mr. Smith was targeting him and the Medical Affairs team; that he wanted Ms. Clark to help him have that behavior stop; and that he wanted to meet with her in person to discuss these concerns in greater depth so that they would end.

157. Ms. Clark never followed up on this complaint; never interviewed Dr. Landis; and took no action of which Dr. Landis is aware, formally or informally, to investigate or address Dr. Landis' concerns.

158. Mr. Smith cut the Medical Affairs budget and staff in FY 2016 and FY 2017, hampering Dr. Landis' ability to execute Medical Affairs components of the corporate project plan in line with industry standard clinical evidence methods.

159. Throughout 2017, Mr. Smith repeatedly excluded Dr. Landis from the Executive Team meetings.

160. On multiple occasions, Mr. Smith held the Executive Team meetings secretly so that Dr. Landis would not know about them.

161. On one occasion, Dr. Landis discovered the entire Executive Team met about the FY 2018 budget without him.

162. On another occasion, Mr. Smith invited, and then uninvited, Dr. Landis to a meeting of the Executive Team at his personal lake home.

163. In the Spring or Summer of 2017, Mr. Smith placed further restrictions on Medical Affairs and Dr. Landis, prohibiting Dr. Landis from engaging any medical consultant for any task, large or small.

164. Mr. Smith was well aware that due to Mr. Smith's prior staffing cuts, Dr. Landis and Medical Affairs relied upon the contributions of such consultants to deliver the team's work.

165. In June 2017, the leadership team met to discuss strategy and budget matters, and Dr. Landis raised, among other concerns, the cut to the consultant budget that would delay product launches.

166. Dr. Landis suggested that, given the strategic directions and budgetary restraints, the majority investor would need to directly face the realities that the Company was facing. Mr. Smith agreed.

167. In or around March 2017, belying the false allegations of Mr. Smith that Dr. Landis was a poor performer or that he had engaged in any inappropriate behavior, Mr. Smith and LLCP, the majority investor in Genova, proposed that Dr. Landis lead a Genova spinoff. During those discussions, Dr. Landis told two Board members directly that Mr. Smith was retaliating against him because of his views regarding compliance and regulatory matters

168. On or about August 2, 2017, at a leadership team meeting, Dr. Landis was asked by the Company's CFO how he viewed the Company's challenges and what he would do about them. Only in response to that direct question did Dr. Landis again, in an entirely professional manner, raise the regulatory and compliance concerns and how he thought the Company should address them.

169. Mr. Smith became visibly angry, accused Dr. Landis of being counterproductive, and sought to shut his comments down. This accusation was immediately refuted by the CFO

who stated to Mr. Smith in front of the leadership team that he did not find Dr. Landis' comments counterproductive.

170. Immediately after, on or about August 3, 2017, Mr. Perlmutter informed Dr. Landis that LLCP and Genova would not proceed with the spinoff company, after Dr. Landis had spent substantial time and his own funds for legal counsel to work on the legal documents and negotiate the proposed transaction.

171. On August 9, 2017, Dr. Landis was unexpectedly summoned to New York to be interviewed by outside counsel for Genova for the first time regarding his compliance concerns.

172. At the conclusion of that meeting, Dr. Landis expressed his concerns (beyond CPT Code 86001 and Code 87798) about three other Company compliance issues and provided counsel with a packet of documents evidencing and supporting these concerns.

173. Dr. Landis has heard nothing further from Genova about his concerns raised in the August 9, 2017 meeting.

174. On August 14, 2017, Dr. Landis was suspended by Mr. Smith, and prohibited from returning to Genova. This suspension was without basis, pretextual, and in retaliation for Dr. Landis' raising his good faith compliance concerns.

175. The Company forbad Dr. Landis from communicating with anyone about his suspension or the Company, so that he could not explain the circumstances and facts to his peers, physicians, customers, and industry contacts outside of the Company.

176. Upon information and belief, Defendants falsely, intentionally, and maliciously misled individuals outside of the Company to believe that Dr. Landis had engaged in misconduct for which he had been suspended.

177. During his suspension, Dr. Landis was interviewed by Genova's outside counsel regarding the alleged bases of his pretextual and retaliatory suspension, but the investigator was not permitted by the Company to investigate Dr. Landis' complaints of retaliation.

178. Dr. Landis remains suspended.

V. FIRST CLAIM FOR RELIEF
Violation of the Federal False Claims Act - § 3729(a)(1)(A)-(B)

179. Relator re-alleges and incorporates by reference the allegations contained in the above Paragraphs of the Complaint.

180. Defendants knowingly presented, or caused to be presented, and continue to present or cause to be presented, materially false and fraudulent claims for payment or approval to the United States and/or its authorized contractors in violation of 31 U.S.C. § 3729(a)(1)(A).

181. Defendants knowingly made or used, or caused to be made or used, false or fraudulent records or statements material to false or fraudulent claims for payment by the United States and/or its authorized contractors in violation of 31 U.S.C. § 3729(a)(1)(B).

182. Defendants presented these false and fraudulent claims and false or fraudulent records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

183. The United States and/or its authorized contractors relied on these false and fraudulent claims and false or fraudulent records or statements, were ignorant of the truth regarding these claims, records and statements, and would not have paid Defendant Genova for these false and fraudulent claims had they known the truth of the falsity of the said false and fraudulent claims, records and statements by these Defendants.

184. As a direct and proximate result of the false and fraudulent claims made by Defendants, the United States and/or its authorized contractors have suffered damages and

therefore are entitled to recovery as provided by the FCA in an amount to be determined at trial, plus a statutorily mandated civil money penalty for each such violation of the FCA.

VI. SECOND CLAIM FOR RELIEF
Violation of the North Carolina False Claims Act

185. Relator re-alleges and incorporates by reference the allegations contained in the above Paragraphs of the Complaint.

186. Defendants knowingly presented, or caused to be presented, and continue to present or cause to be presented, materially false and fraudulent claims for payment or approval to the State of North Carolina and/or its authorized contractors in violation of N.C. Gen. Stat. §1-607(a).

187. Defendants knowingly made or used, or caused to be made or used, false or fraudulent records or statements material to false or fraudulent claims for payment by the United States and/or its authorized contractors in violation of N.C. Gen. Stat. §1-607(b).

188. Defendants presented these false and fraudulent claims and false or fraudulent records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

189. The United States and/or its authorized contractors relied on these false and fraudulent claims and false or fraudulent records or statements, were ignorant of the truth regarding these claims, records and statements, and would not have paid Defendant Genova for these false and fraudulent claims had they known the truth of the falsity of the said false and fraudulent claims, records and statements by these Defendants.

190. As a direct and proximate result of the false and fraudulent claims made by Defendants, the United States and/or its authorized contractors have suffered damages and

therefore are entitled to recovery as provided by the FCA in an amount to be determined at trial, plus a statutorily mandated civil money penalty for each such violation of the FCA.

VII. THIRD CLAIM FOR RELIEF
Unlawful Retaliation - 31 U.S.C. § 3730(h)

191. Relator re-alleges and incorporates by reference the allegations contained in the above Paragraphs of the Complaint.

192. Relator has been an employee of Genova Diagnostics, Inc. since 2012.

193. As detailed above, Relator took numerous acts in furtherance of a potential claim under the Federal False Claims Act, including notifying Geneva's management of issues regarding the company's fraudulent Medicare billing practices.

194. Defendants knew of Relator's actions.

195. Defendants retaliated against Relator by, inter alia, interfering with his ability to discharge his duties as Genova's Chief Medical Officer, undermining Relator's status with the company and, ultimately, suspending Relator without basis or good cause.

196. As a result of Defendants unlawful retaliation, Relator has suffered damages in an amount to be determined at trial.

VIII. FOURTH CLAIM FOR RELIEF
Unlawful Retaliation - N.C. Gen. Stat. § 1-613

197. Relator re-alleges and incorporates by reference the allegations contained in the above Paragraphs of the Complaint.

198. Relator has been an employee of Genova Diagnostics, Inc. since 2012.

199. As detailed above, Relator took numerous acts in furtherance of a potential claim under the North Carolina False Claims Act, including notifying Geneva's management of issues regarding the company's fraudulent Medicaid billing practices.

200. Defendants knew of Relator's actions.

201. Defendants retaliated against Relator by, inter alia, interfering with his ability to discharge his duties as Genova's Chief Medical Officer, undermining Relator's status with the company and, ultimately, suspending Relator without basis or good cause.

202. As a result of Defendants unlawful retaliation, Relator has suffered damages in an amount to be determined at trial.

WHEREFORE, Relator Darryl Landis requests the following relief:

1. For judgment that:

   a. Defendants have violated the Federal False Claims Act;

   b. Defendants have violated the North Carolina False Claims Act;

   c. Defendants have unlawfully retaliated against Relator in violation of 31 U.S.C. § 3730(h);

   d. Defendants have unlawfully retaliated against Relator in violation of N.C. Gen. Stat. § 1-613;

2. That the United States of America be awarded its actual damages, trebled pursuant to 31 U.S.C. § 3729 *et. seq.*; plus applicable civil money penalties;

3. That the State of North Carolina be awarded its actual damages, trebled pursuant to N.C. Gen. Stat. § 1-605 *et. seq.*, plus applicable civil money penalties;

4. That Relator be awarded a portion of any recovery by the United States of America and/or the State of North Carolina as provided by 31 U.S.C. § 3729 *et. seq.* and N.C. Gen. Stat. § 1-605 *et. seq.*;

5. That Relator be awarded its costs in this civil action, including reasonable attorneys' fees and expenses;

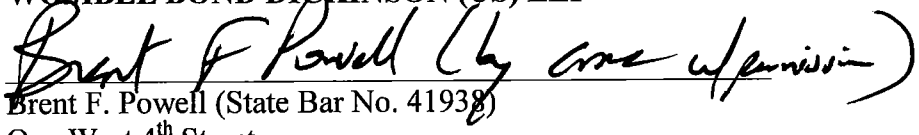
6. That Relator be awarded damages allowed under 31 U.S.C. § 3730(h) and N.C. Gen. Stat. § 1-63 and other applicable law and statutes;

7. That this matter be tried by jury; and

8. That Relator be awarded such other and further relief as the Court may deem just and proper.

This 15th day of December 2017

WOMBLE BOND DICKINSON (US) LLP



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**Appearing pursuant to Local Civil Rule 83.1*

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